

K030211

JUN 13 2003

## 510 (k) SUMMARY (21 CFR PART 807.92)

### Product

Rapid Barbiturate Test Strip and Rapid Barbiturate Test Card

### Name of Manufacturer

Rapid Diagnostics, Division of ICN BIOMedicals Inc.  
1429 Rollins Road, Burlingame, CA 94010, U.S.A.

### Principle

The RapidBAR test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding anti-barbiturate antibody between barbiturate-protein conjugate and free drug which may be present in the urine specimen being tested.

When barbiturate is present in the urine specimen, it competes with barbiturate-protein conjugate for the limited amount of mouse anti-barbiturate MAb-colloidal gold conjugate. When the amount of barbiturate is equal or more than the cut-off, it will prevent the binding of barbiturate-protein conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line composed of Goat anti-Mouse IgG antibody is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

### Intended Use

The RapidBarbiturate Tests are immunochromatography based one step *in vitro* test. It is designed for qualitative determination of secobarbital in human urine specimen above the cutoff level of 300 ng/ml.

### Performance

The studies performed are listed below:

Rapid Barbiturate Test Strip  
Sensitivity  
Accuracy (comparison study of clinical urine specimens)

Stability – Specimen  
Stability – Product  
Precision  
Reproducibility  
Specificity  
Interference

Rapid Barbiturate Test Card

Accuracy (comparison study of clinical urine specimens)

Precision

Comparison between Rapid Barbiturate Test Strip and Test Card

Both urine control specimen and clinical urine specimen were tested to evaluate the safety and effectiveness of Rapid Barbiturate Test Strip and Rapid Barbiturate Test Card.

The results of performance characteristics demonstrate Rapid Barbiturate Test Strip and Rapid Barbiturate Test Card to be substantially equivalent to the Applied Biotech ***SureStep™* Drug Screen Test Barbiturate**, which received 510 (k) approval.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 13 2003

Mr. Charles Yu  
Director of Technical Operation  
ICN Biomedicals, Inc.  
1429 Rollins Road  
Burlingame, CA 94010

Re: k030211  
Trade/Device Name: Rapid Barbiturate Test Strip  
Rapid Barbiturate Test Card  
Regulation Number: 21 CFR 862.3150  
Regulation Name: Barbiturate Test System  
Regulatory Class: Class II  
Product Code: DKX  
Dated: April 11, 2003  
Received: April 16, 2003

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

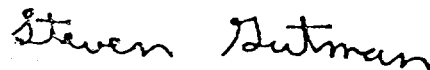
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510 (K) number (if known): K030211

Device Name: Rapid Barbiturate Test Strip

Indications for Use:

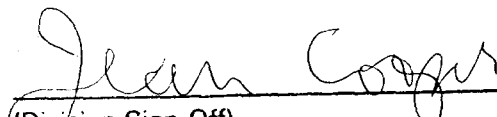
Rapid Barbiturate Test Strip is an immunochromatography based one step *in vitro* test. It is designed for qualitative determination of Barbiturate and its metabolites in human urine specimens. The presence of secobarbital in human urine above a cutoff level of 300ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

This test provides only a preliminary analytical test result. A more specific chemical method, such as GC/MS, must be used in order to obtain a confirmed analytical result.

---

Concurrence of the CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K030211

Prescription Use: ✓  
(Per 21 CFR 801.109)

OR

Over the Counter Use: \_\_\_\_\_

## INDICATIONS FOR USE STATEMENT

510 (K) number (if known): K030211

Device Name: Rapid Barbiturate Test Card

Indications for Use:

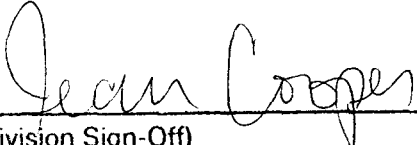
Rapid Barbiturate Test Card is an immunochromatography based one step *in vitro* test. It is designed for qualitative determination of Barbiturate and its metabolites in human urine specimens. The presence of secobarbital in human urine above a cutoff level of 300ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

This test provides only a preliminary analytical test result. A more specific chemical method, such as GC/MS, must be used in order to obtain a confirmed analytical result.

---

Concurrence of the CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K030211

Prescription Use: ☒   
(Per 21 CFR 801.109)

OR

Over the Counter Use: ☐